JOHN WARD CYBERSECURITY BLOGS

YOUR ONLINE RESOURCE FOR TIMELY ANALYSIS, COMMENTARY AND RESOURCES TO KEEP YOU INFORMED ON THE RAPIDLY EVOLVING AND CRITICAL FIELD OF CYBERSECURITY

John Ward – Cyberblog March 2024
KEY TAKEAWAYS ON NEW FDA CYBERSECURITY DRAFT GUIDANCE

A NEW DRAFT GUIDANCE

September 2023 saw the introduction of *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, a finalized guidance by FDA that superseded previous draft guidance and provided medical device manufacturers (MDMs) with FDA's current thinking on meeting the legal requirements of the newly amended FD&C Act (Section 524B). Section 524B has been covered extensively in this blog series and was a significant moment in the regulatory landscape, both for the immediate tangible requirements that MDMs were now responsible in premarket submission documentation and for the framework that was provided for the future. Section 524B(e) establishes that premarket submission guidance for cybersecurity will be updated "Not later than 2 years after the date of this enactment, and periodically thereafter" the FDA premarket cybersecurity guidance will be updated. This represents a focus on keeping guidance current with cybersecurity threats that evolve rapidly and continue to proliferate in the healthcare sector. On March 13th, 2024, the first of these proposed updates was released.

SELECT UPDATES FOR THE PREMARKET CYBERSECURITY GUIDANCE: Section 524B of the FD&C Act

The new draft guidance is titled *Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act*. As a draft guidance it does not supersede the recommendations provided in *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, which is a finalized guidance. The new draft guidance, in accordance with Section 524B(e), is now in a 60 day window in which stakeholders can submit comments and suggestions before it is ultimately synthesized into *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

The new draft guidance proposes an additional section to *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, titled "Section II: Cyber Devices". Of immediate note is the fact that this draft guidance does not propose any new deliverables for MDMs to submit as part of their cybersecurity premarket submission documentation. Rather, in the opinion of the author, this draft guidance clarifies some aspects of the finalized guidance as well as providing more direct alignment and recommendations with the language in Section 524B. As the regulatory landscape adapts to the augmentation of FDA's statutory authority in regard to medical device cybersecurity it appears that FDA are taking lessons learned from premarket submissions and feedback items since Section 524B began to be enforced and proposing updated guidance to address trends or concerns that they have observed.

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At eight pages the draft guidance will not serve as an exhaustive supplement or addition to the finalized guidance but MDMs are encouraged to familiarize themselves with the draft guidance at this stage as it does provide some important clarifications and information, and it is likely to be implemented in some form into the final guidance.

"CYBER DEVICE"

Among the more significant portions of the draft guidance is "Section II. B. Devices Subject to Section 524B of the FD&C Act". Among the more common questions Ward Sciences and Consulting receives is whether an MDMs device qualifies as a "cyber device" and thus whether they need to provide cybersecurity documentation in their premarket submission. In our experience this line of thinking is supported by ambiguous alignment between the finalized premarket guidance as it currently exists and the language of Section 524B(c) which states that a cyber device is a device that "(1) includes software validated, installed, or authorized by the sponsor as a device or in a device; (2) has the ability to connect to the internet; and (3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats". The current Section "II. Scope" of the finalized premarket guidance states "This guidance document is applicable to devices with cybersecurity considerations, including but not limited to devices that have a device software function or that contain software (including firmware) or programmable logic. The guidance is not limited to devices that are network-enabled or contain other connected capabilities". The new draft guidance provides clearer alignment with Section 524B and more detailed criteria regarding what FDA considers a "cyber device".

"REASONABLE ASSURANCE OF CYBERSECURITY"

MDMs who have received feedback from FDA following the submission of their premarket submission will likely be familiar with the phrase "…does not provide a reasonable assurance of cybersecurity". Among the more direct statutory requirements of Section 524B (Coordinated Vulnerability Disclosure, Patching/Updating), the provision that manufacturers of cyber devices "design, develop and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure…". In the experience of Ward Sciences and Consulting this provision has served as the basis for a wide range of feedback items on cybersecurity premarket submissions. The draft guidance provides some additional detail into how FDA is evaluating premarket submission documentation in relation to this provision.

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MORE TO COME

Since the amendment of the FD&C Act MDMs have learned that they must be dynamic in responding to statutory and regulatory changes regarding cybersecurity. The finalized guidance in September 2023 and the draft guidance in March of this month both came as surprises for many. It is important to adjust your policies, procedures, protocols and overall strategy to meet the current regulatory landscape not only as it exists, but as it changes. It was identified earlier in this blog that updating the finalized premarket cybersecurity guidance is a provision of the amended FD&C Act. While this new draft guidance has not been finalized it represents the rapidity and suddenness in which regulatory strategy can change, and it is recommended that MDMs recognize there will be more changes on the way.

The draft guidance is located here: https://www.fda.gov/media/176944/download. In addition to the topics discussed in this blog, the draft guidance also addresses SBOM, Cybersecurity Management Plans, and modifications. We will be discussing these topics in future blogs.

Key Takeaways for this New FDA Cybersecurity Draft Guidance

- The new draft guidance indicates how FDA is evaluating premarket cybersecurity submission documentation and provides clarity in aligning premarket submissions documentation with Section 524B.
- Although the proposed additions to the final guidance are not yet finalized MDMs would be wise to synthesize the recommendations contained in the new draft guidance into their in-progress or planned premarket submissions.
- Section 524B established that the final guidance would be updated as needed. The draft guidance is the first proposed update but is likely not the last. Now is the time for MDMs to establish processes for notification of proposed guidance updates and implementation in the design and development process of their medical devices.
- Your voice matters! Comments and suggestions regarding the proposed changes can be sent to FDA at https://www.regulations.gov/ for 60 days from the publication in the *Federal Register* of the notice announcing the availability of the draft guidance.

END OF MARCH 2024 BLOG